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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SHIBUYA, MARK LANCE	

ART UNIT	PAPER NUMBER
1639	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,756	KOZLOWSKI ET AL.	
	Examiner	Art Unit	
	Mark L. Shibuya, Ph.D.	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/22/2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-15* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Application No. 10/506,756 (20050181449 A1): Claims 1-15 are pending.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-7, drawn to an array comprising a surface having attached at least one cytosolic accessory protein.

Group II, claim(s) 8-12, drawn to methods for determining cytosolic accessory protein interaction with a given membrane, for screening compounds or peptides or proteins for the ability to interact selectively with a cytosolic accessory protein.

Group III, claim(s) 13, drawn to the use of an array of cytosolic accessory proteins to measure the relative catalytic activity of different members of a family of accessory proteins.

Group IV, claim(s) 14, drawn to the use of an array of cytosolic accessory proteins as an affinity surface on which to select antibodies from a library of phenotype-genotype-linked antibodies (e.g. phage displayed antibodies).

Group V, claim(s) 15, drawn to the use of an array of cytosolic accessory proteins for determining the effect of post-translational modifications on the interactions of accessory proteins with membrane proteins and/or on the properties of said membrane proteins.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

US 20020188104 A1, discloses arrays (96 well plates) containing isolated cytosol, which would inherently comprise cytosolic accessory proteins, (as evidenced by Shisheva, Methods In Enzymology, (2001), Vol. 329, 39-50, at, e.g., p. 43; Leung et al., J. Biol. Chem. (Jan. 31, 1997), Vol. 272 (5), 2607-2614, at e.g., the abstract; Zarsky et al., FEBS Letters (1997) vol. 403, 303-308, at, e.g., the abstract) and states:

> [0070] In addition to the above-described binding assays, function-based assays can also be used to screen test compounds for potential use as hRpr agonists or antagonists. Compounds that enhance or inhibit hRpr-induced apoptosis can be screened for based on the observation that hRpr, like its Drosophila counterpart, can act in conjunction with cytosolic factors to trigger cytochrome c release from the mitochondria (Evans et al, EMBO J. 16:7372-7381 (1997)). For example, mitochondria purified from Xenopus egg extracts can be aliquoted into 96-well plates. Isolated cytosol (e.g., prepared in parallel from Xenopus eggs) or cytosol immunodepleted of the hRpr-interacting protein, Scythe, can be added to the wells. This array can then be used to screen test compounds for their ability to trigger cytochrome c release from mitochondria in the presence of Scythe (i.e., Reaper-mimetics) or to screen test compounds for their ability to enhance or inhibit cytochrome c release upon addition of hRpr (e.g., recombinant). Cytochrome c release can be measured via an ELISA using anti-cytochrome c antibodies or fluorometrically using mitochondria pre-loaded with GFP-cytochrome c (Goldstein et al, Nature Cell Biol. 2:156 (2000)).

US 20020055125 A1, discloses arrays of samples derived from cytosol, which would inherently comprise cytosolic accessory proteins, (as evidenced by Shisheva, Methods In Enzymology, (2001), Vol. 329, 39-50, at, e.g., p. 43; Leung et al., J. Biol. Chem. (Jan. 31, 1997), Vol. 272 (5), 2607-2614, at e.g., the abstract; Zarsky et al., FEBS Letters (1997) vol. 403, 303-308, at, e.g., the abstract), and state:

> [0104] In particular, arrays in accordance with the present invention are useful in performing proteomic analyses of complex protein samples. As used herein, proteomics is the separation and/or quantitation and/or identification of one or more proteins in a sample. The sample may be

> derived from a cell (e.g., the cell's cytosol, membrane or extra-cellular proteins), tissues (e.g., dissected or laser-microdissected), body fluids (such as urine, blood spinal fluid) or any other sample containing proteins. The results of such separation/quantitation/identification may produce novel protein targets for drug screening, proteins for diagnostics, or novel synthetic ligands for assays or protein purification. The arrays may very effectively be used in differential protein binding assays. For example, two (or more)-color fluorescent labeling of complex protein mixtures, and the analysis of differential protein binding to the array by fluorescence imaging may be conducted. As described below, the arrays may be used in conjunction with other techniques to identify, sequence and structurally characterize differentially expressed proteins or peptides of interest. The arrays may be run in parallel with DNA arrays and the differential binding results compared to identify correlations between gene activity and protein expression. Also, mixed arrays, wherein the molecules making up an array includes antibodies, etc. may be prepared and used to conduct binding assays.

US 20010041349 A1, discloses arrays of recombinant cytosolic proteins, which would inherently comprise cytosolic accessory proteins, (as evidenced by Shisheva, Methods In Enzymology, (2001), Vol. 329, 39-50, at, e.g., p. 43; Leung et al., J. Biol. Chem. (Jan. 31, 1997), Vol. 272 (5), 2607-2614, at e.g., the abstract; Zarsky et al., FEBS Letters (1997) vol. 403, 303-308, at, e.g., the abstract), and states:

> [0041] Recombinant proteins may be assayed either in the expression array, or after transfer of the proteins to a second array format. For example, an array of protein expression systems may be distributed in the wells of a microtiter-like array. Referring now to FIG. 3, in the case of soluble protein 40 secreted from cells 42, the presence of the protein may be evaluated directly in the well 46, or after transfer of the secreted components to another well 48 (FIG. 3A, bottom and top panels, respectively). Similarly, where the soluble protein is cytosolic, the cells may be lysed and the recombinant protein measured directly in the well, or after transfer of the secreted components to another well. In either case, detection of expressed protein does not compromise isolation of the plasmid/phagemid DNA from each site of the array. Thus, for the array site which provides an interaction of interest, the recombinant DNA can be isolated and propagated for further characterization.

Therefore there is no special technical feature linking the claims.

Election of Species

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

A family of cytosolic accessory protein

A family of homologous membrane proteins

A method for determining cytosolic accessory proteins that interact with a given membrane protein; a method for screening compounds for the ability to interact selectively with a cytosolic accessory protein; or a method for screening compound for the ability to selectively modulate the interaction between a cytosolic accessory protein and a membrane protein.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims

subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

A family of cytosolic accessory protein: Claims 1-7

A family of homologous membrane proteins: Claims 1-7

A method for determining cytosolic accessory proteins that interact with a given membrane protein; a method for screening compounds for the ability to interact selectively with a cytosolic accessory protein; or a method for screening compound for the ability to selectively modulate the interaction between a cytosolic accessory protein and a membrane protein: Claims 8-12.

The following claim(s) are generic: Claims 1-7.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Shisheva, Methods In Enzymology, (2001), Vol. 329, 39-50, at, e.g., p. 43; and Zarsky et al., FEBS Letters (1997) vol. 403, 303-308, at, e.g., the abstract), teach cytosolic accessory protein that is GDP dissociation inhibitor (GDI) proteins.

US 20020055125 A1 teaches assaying for compounds that interact with a cytosolic accessory protein.

Walke et al., WO 01/68869 (IDS, entered 2/22/2006, citation B4), see entire publication, especially pp. 5-6, disclose arrays of a cytosolic accessory protein, which is

a G-coupled protein receptor kinase, for a homologous membrane protein that is a G-coupled protein receptor kinase.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Shibuya, whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. J. Douglas Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Primary Examiner
Art Unit 1639